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20 UNITED STATES DISTRICT COURT
 21 NORTHERN DISTRICT OF CALIFORNIA,
 22 SAN FRANCISCO DIVISION

23 GUARDANT HEALTH, INC.,

24 Plaintiff and Counterclaim-
 Defendant,

25 vs.

26 NATERA, INC.,

27 Defendant and Counterclaim-
 28 Plaintiff.

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Case No. 3:21-cv-04062-EMC

**JOINT SUBMISSION RE OBJECTIONS
 REGARDING CLOSINGS [TRIAL TR.
 1954]**

Guardant's Objections to Natera's Closing Slides

Guardant's Position: As set forth in Dkt. 823, Guardant's Motion for Sanctions for Natera's Continued Misconduct with Respect to the Exchange of Closing Demonstrative Slides, Natera's bad-faith gamesmanship made it impossible for Guardant to meaningfully review Natera's proposed demonstrative slides for closing. At 6:31 pm on Wednesday, November 20, Natera sent to Guardant's counsel a link to a slide set of 321 demonstrative slides. As noted in Guardant's Motion, many of those were, facially, objectionable. However, there were no means by which Guardant's counsel could reasonably review the slides in any detail to determine whether they accurately cited to and characterized evidence in the record, or otherwise raising arguments this Court held are off-limits. Guardant directed Natera to provide a reduced set of no more than 100 slides no later than 11:00 pm. Natera's counsel failed to do so, and instead provided a set of 199 slides at a minute before midnight that evening. Natera's counsel's forwarding email indicated that slides had been withdrawn and modified, and an expedited review showed that at least one slide had been added. Natera's counsel further modified the deck at 10:16 am Thursday morning.

Guardant respectfully restates its position that the sheer volume of Natera's slides, submitted, changed, and resubmitted, makes an adequate review impossible, and again states that exclusion of the demonstratives entirely is an appropriate sanction. However, Guardant does its best herein to preserve its objections.¹

Natera's Position: Natera opposed Guardant's motion for sanctions earlier today, because Guardant refused to meet and confer about these issues before filing its motion. Dkt. 826. Although Guardant refused to meet and confer about Natera's slides last night, refused to meet and confer this morning, and then refused to share any of its objections to Natera's slides until the parties' meet and confer this afternoon, Guardant clearly had been preparing this extremely lengthy narrative of objections, which it shared with Natera for the first time at 4:32 p.m. (ahead of the 5:00 p.m. filing deadline). Natera has attempted to insert its responses to these objections as best

¹ References to "Natera Slide No." are based on Natera's original submission of 321 slides. In resubmitting its slide set at midnight, Natera retained the original slide numbers. Thus, while the objections refer to the original deck's numbering, the objections refer to slides Natera claims it intends to use during closing.

1 it can on the Court's deadline, but Guardant's conduct in refusing meet and confer until ordered
2 again by the Court and withholding its detailed objections from Natera until last minute is in bad
3 faith.

4 Guardant's objections are primarily not to the form of the slides, or whether certain pieces
5 of evidence have been admitted, but rather to Natera's theory of the case. In short, Guardant's
6 remaining objections are aimed at artificially circumscribing the arguments that Natera may
7 present to the jury; they are not valid objections to Natera's closing demonstratives. Natera has
8 revised its slides to address any legitimate objections Guardant raised during the parties' meet and
9 confer.²

10 **Guardant's Position: *MolDX Slides*.** Natera Slide Nos. 8, 9, 12, 36, 37, 38, 39, 40, 145,
11 146, 147, 148, , 278, 291, and 292, .


12 Perhaps the most serious issue with Natera's slide deck is its repeated use of documents
13 referring to Guardant's submissions to MolDX. The Court has made it clear that MolDX's mindset
14 and reasons for delaying coverage of Medicare for Reveal is not an issue to be raised with this
15 jury. E.g., Dkt. 509 at 9. In this same vein, the Court made clear that communications with MolDX
16 are not "advertising." *Id.* at 7 ("statements to MolDX were not directed at or received by
17 consumers, they are not actionable under the Lanham Act").

18 Despite this Court's clear holdings on each of these points, Natera's slide deck is riddled
19 with references to Guardant's communications with MolDX, as well as Guardant's internal
20 assessment of its pending application for Medicare coverage. None of this is properly the subject
21 of closing arguments, and should be excluded.

22 Examples of Natera's misuse of MolDX documents begins early, at Natera Slide No. 8
23 (which is actually the fourth of its current set):

27 ² At the same time Natera was preparing its response to Guardant's argument in the 28 minutes it had before
28 the filing deadline, it also revised certain slides to attempt to address Guardant's last-minute objections.
Guardant told Natera to assume that it was maintaining its objections to all of the slides Natera revised.


Natera's Ads Compare the Parikh and Reinert Studies Just Like Guardant Did



Signatera vs. Reveal performance comparison

	Signatera	Reveal
Validation data published or presented (# patients analyzed)	> 2,000 ^{1,2}	< 150 ³
Pre-surgical sensitivity in CRC	89-94% ^{1,2}	47% ³
Failure rate in CRC – tissue and plasma combined	< 3% ¹	12-14% ³
Number of blood tubes required	2	4
Diagnostic lead time vs. radiographic recurrence in CRC (avg)	8.7 months ⁴	<4 months ⁵
Post-surgical NPV/PPV in CRC (30 days post-surgery)	88% / 100% ^{1,2}	not reported ³
Serial longitudinal NPV in CRC	97% ¹	92% ³
Serial longitudinal Hazard Ratio in CRC	43.5 ¹	11.4 ³
Serial longitudinal sensitivity in CRC	88-94% ^{1,2}	69% ³
Quantitation of ctDNA burden for monitoring purposes	Tumor copies per mL	none

TX-126



GH CRC MRD Test Meets LCD Requirements

Performance Parameter	Signatera (Reinert et al)	Guardant (Parikh, et al)
Landmark sensitivity	92% (7/4)	96% (15/7)
Single post-treatment treatment	88% (14/16)	91% (20/22)
Surveillance sensitivity	98% (58/59)	100% (27/27)
Specificity	93% (14/15)	100% (27/27)
# ctDNA at recurrence free	93% (14/15)	100% (27/27)
PPV	8.7mo	6.9mo
Lead time	69% / 64% (surveillance)	35% / 81% (benchmark)

GH CRC MRD Test meets the LCD Requirements:

- Identifies recurrence prior to radiographic recurrence
- Sensitivity/Specificity better than CEA
- Performance similar to Signatera

TX-585.7

DDX10.8

The characterization of Guardant's submission to MolDX as an "ad" is literally false, and directly contravenes this Court's analysis that statements to MolDX are *not advertising*. Dkt. 509 at 7. Natera Slide No. 9 duplicates the MolDX image on the right among other MolDX, non-advertising documents, while Natera Slide No. 145 portrays the image, with an inset of the cover of the document, under the heading: "Guardant Compared the Two Studies Long Before Natera's Ads"—not only suggesting this is an advertisement, but also showing that it took MolDX a very long time to approve coverage. Natera Slide No. 148 again uses this image, paired with Dr. Heitjan's testimony that it was a "red apple to a green apple" comparison, and uses it again in Slide No. 315.

Natera Slide No. 12 falls within *both* uses of MolDX documents excluded by this Court. It is an excerpt from an internal Guardant communication discussing the pending MolDX coverage submission, and characterizes Natera's anti-Reveal campaign as a "respon[se] to Guardant's Ads that Are Based on 'Terrible' Data":

Natera's Ads Responded to Guardant's Ads that Are Based on "Terrible" Data



Related to Signatera, I am highly frustrated since their Reinert study isn't great either. What it did do that ours didn't is follow more patients longitudinally. There might be some veiled/unspoken concern our specificity is not as good as we make it out to be since we didn't test much longitudinally. But I also share Medicare's worry that our preop sensitivity of 46% is quite terrible and not expected. The Reinert preop is 86%. I share Medicare's concern that how can you expect the assay to perform well in a minimum residual use case, if it cannot perform well when the tumor is known to exist in the body. I don't think it is an assay problem, more a data problem with sample quality as the culprit.

TX-612.1

DDX10.12

This is not an "ad," and instead discusses at length Guardant's assessment of MolDX's decision-making processes and reasons for the delay in Medicare coverage. It is improper for Natera to characterize it at all, and wholly improper to *mischaracterize* it. Natera returns to this same image in Natera Slide No. 186, this time with the misleading heading "Pre-Surgical Sensitivity Is an Important Indication of the Test's Ability to Perform Well in an MRD Use Case." In this same vein, Slide Nos. 291 and 292 characterize Mr. McCoy's "agreement" with "the concerns Natera sent to Medicare."

Natera Slide No. 35 discusses the scope of Signatera's Medicare coverage (presumably to argue it is broader than Reveal's. And to drive that point home, Natera Slide No. 293 states: "Natera's concerns about surveillance data were valid; Guardant was not granted Medicare Coverage for surveillance."

Natera's Concerns About Surveillance Data Were Valid; Guardant Was Not Granted Medicare Coverage For Surveillance



Mark McCoy
Senior VP

A. So we do not have coverage for a single time point test.

And -- and -- sorry. We do not have coverage for any test that is ordered outside the three-month curative intent therapy window, and we do not have coverage unless it's ordered as a bundle.

Q. And you did seek coverage for those?

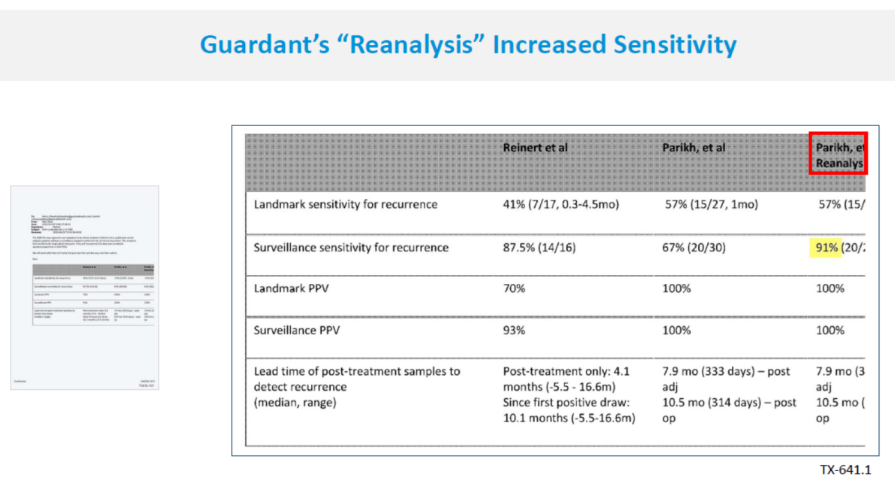
A. Yeah. We sought coverage that was similar to the Signatera assay.

Day 7 Trial Tr. 1578:8-15

Natera Slides No. 36, 37, 38, 39, and 40 all pertain to Guardant's request for Medicare coverage, and Natera's characterization of a "data gap" that prevented approval. This all goes to the question of *whether* MolDX should have approved Reveal for coverage, and the timing as to *when* coverage would be granted—none of which was relevant. Moreover the Court explicitly prohibited and warned Natera from introducing any evidence of the supposed data gap in connection with MolDX. Tr. 317:20-318:1 ("If you introduce any kind of evidence that suggests that there was a data gap and that was the reason, that would open the door. If you . . . it's a warning that if you [do] get into that in terms of evidence, we may be talking about a different ballgame.")

Natera Slide No. 46 again concerns Guardant's submission of data to MolDX, and this time at least insinuates that the data were untrustworthy:

Guardant's "Reanalysis" Increased Sensitivity

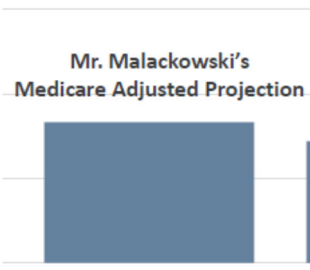


	Reinert et al	Parikh, et al	Parikh, et al Reanalysis
Landmark sensitivity for recurrence	41% (7/17, 0.3-4.5mo)	57% (15/27, 1mo)	57% (15/27)
Surveillance sensitivity for recurrence	87.5% (14/16)	67% (20/30)	91% (20/22)
Landmark PPV	70%	100%	100%
Surveillance PPV	93%	100%	100%
Lead time of post-treatment samples to detect recurrence (median, range)	Post-treatment only: 4.1 months (-5.5 - 16.6m) Since first positive draw: 10.1 months (-5.5-16.6m)	7.9 mo (333 days) – post adj 10.5 mo (314 days) – post op	7.9 mo (333 days) – post adj 10.5 mo (314 days) – post op

TX-G41.1

Natera Slide No. 146 includes testimony from Dr. Odegaard regarding MolDX's requirements for Guardant's submission for Medicare coverage, and Natera Slide No. 147 continues with Dr. Odegaard's testimony that Guardant's comparisons *in connection with Medicare approval* were not "false or misleading."

Natera Slide No. 259 is an image of a scale showing "Full Medicare Coverage" on one arm, while Natera Slide No. 278 includes a bar chart from an opinion that has been rooted out of the case:



None of these MolDX materials should be used as demonstratives with the jury.

Natera's Response regarding slides 8, 9, 145, 146, 147, 148. Guardant has repeatedly objected to Natera's use of this evidence showing that Guardant compared the Parikh and Reinert studies, and the Court has consistently overruled those objections. The exhibits are not being depicted as "ads" and Natera will not argue they are "ads." TX-585 (from slide 8), for instance, was used in Natera's opening statement, and the Court already overruled Guardant's same objections to this same exhibit multiple times. See Dkt. 778 at 1; Dkt. 779 at 10 (evidence relevant to state of mind). The Court has already ruled that Natera may rely on Guardant's statements to MolDX to show that Guardant has made the same comparisons between the Reinert and Parikh studies. Day 6 Trial Tr. at 1199:3-8 ("And, by the way, let me make a comment about MolDX stuff. That has been coming in. I've allowed a fair amount of that. Just a reminder, I allowed that for a narrow door to go to the intent of Natera and maybe to explain this little argument on: Well, you compared them in a chart from MolDX and we had to do that."). That is the purpose of these demonstratives, and the purpose of the evidence that the Court admitted over Guardant's objections (or where Guardant withdrew or waived its objections): to show that notwithstanding Guardant's claims in this litigation that comparisons between the Parikh and Reinert studies are "false and misleading" because the studies are not comparable, Guardant itself constantly made these same comparisons itself, and saw no problem in doing so when Guardant believed it would work to Guardant's advantage. Natera is entitled—and the Court has already ruled—that Natera is permitted to demonstrate this inconsistency in Guardant's position.

Natera's Response regarding slides 12, 35, 36, 37, 38, 39, 40, 259 (revised), 278, 291, 292, 293, 315. As to Mr. McCoy's communications and testimony—which were also admitted over the same objection that Guardant reasserts here—those show that Guardant agreed that the data in the Parikh study was "terrible" (among other things), and these internal acknowledgements

are exactly in alignment with the criticisms Natera raised before and that it is asserting in this trial. That these documents were in the context of submitting or responding to information from MolDX does not render them excluded; indeed, the Court has already admitted these exhibits and permitted witnesses to testify about them. The Court has further permitted testimony regarding Signatera obtaining Medicare coverage prior to Reveal, and that Reveal did not obtain the same level of Medicare coverage as Signatera.

Natera's Response regarding slides 36-40, 145, 186, 202.

Guardant's intent to "fast follow" Signatera's LCD. The underlying exhibits (TX-1369 and TX-603) have been admitted in evidence. Natera does not intend to argue that Reveal did not receive Medicare coverage because of its lack of data. Rather, these are internal Guardant emails, from long before Guardant's submission to MolDx, and they are unrelated to MolDx's decision to cover or not cover Reveal. Rather, these admitted exhibits and testimony demonstrate Guardant's recognition that it did not have data to support the same claims it made in its at-issue advertisements.

Guardant's Position: *Misleading Use of non-advertising.* Natera Slide Nos. 11, 49, 127, 128, 130, 311. The Court has made it clear that communications to investors are *not* advertising:

Statement not made to consumers but which simply have an eventual impact upon purchasing behavior do not fall under the Act. For example, in *Sigma Dynamics, Inc. v. E. Piphany, Inc.*, the court found that statements made to primarily influence investors, rather than consumers, but which could ultimately influence consumers, were not cognizable under the Lanham Act. 2004 WL 2648370 at *3 (N.D. Cal. 2004). There, the defendant had made statements to investors during earnings conference calls, for the purpose of reporting the defendant's financial condition. *Id.* The court dismissed these claims, in part because plaintiffs failed to allege that consumers attended the conference calls. *Id.* Thus "[s]tatements made during an earnings conference call primarily to influence investors that may have an incidental effect of promoting goods to customers are not within the reach of the Lanham Act." *Id.* (citing *Rice v. Fox Broad. Co.*, 330 F.3d 1170, 1181 (9th Cir. 2003), overruled on other grounds by *Skidmore as Tr. For Randy Craig Wolfe Tr. V. Led Zeppelin*, 952 F.3d 1051 (9th Cir. 2020)). See also *Tercica, Inc. v. Insmed Inc.*, 2006 WL 1626930, at *17-18 (N.D. Cal. June 9, 2006) (no claim where statements were made to potential investors during conference calls and in press releases because no consumer attended the call). The Lanham Act requires that the communication be directed at or received by consumers.

Dkt. 509 at 5-6; *see also* Dkt. 822. Moreover, statements "must be disseminated sufficiently to the

1 relevant purchasing public to constitute ‘advertising’ or ‘promotion’ within that industry.” *Coastal*
 2 *Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999). “A handful of
 3 statements to customers does not trigger protection from the Lanham Act unless ‘the potential
 4 purchasers in the market are relatively limited in number,’ which is not the case here.” *Walker &*
 5 *Zanger, Inc. v. Paragon Indus., Inc.*, 549 F. Supp. 2d 1168, 1182 (N.D. Cal. 2007) (quoting *Coastal*
 6 *Abstract*, and granting summary judgment of no false advertising); *see also Brion Jeannette*
 7 *Architecture v. KTGy Grp. Inc.*, No. 07-cv-00691, 2009 WL 10673200, at *4 n.2 (C.D. Cal. July
 8 30, 2009) (“One person is not a sufficient segment of an entire market.”).

9 Here, Natera titles its slides as suggesting that non-advertising statements were
 10 “advertising.” In Natera Slide No. 11, Natera has an image of an internal Guardant document, with
 11 the statement: “Natera Ads Responded to Guardant’s Ads that Are based on Misleading and Buried
 12 Data.” But the document cited is an internal Guardant email dated September 2020—long before
 13 there was any Guardant “advertising” at all. Slide No. 49 refers to an internal Natera email
 14 complaining about Guardant’s presentation at the JP Morgan conference. But it is undisputed that
 15 JPMorgan is an annual conference held here in San Francisco with investors and companies
 16 presenting their – some of their data.” Masukawa, Trial Tr. 655-56. It is not “advertising.” *See also*
 17 Natera Slide No. 128 (taking Ms. Price’s testimony about “targeting Signatera users” out of
 18 context, and asserting this was associated with the “JP Morgan Conference”).

19 Natera Slide Nos. 127 and 311 refer to TX-554, an email from Mr. Marcus Outzen
 20 discussing the then-recent Harvard Study. Both references are misleading and improper; the
 21 Outzen email had never been approved, Price, Trial Tr. 481:8-19, and Ms. Price also testified that
 22 “this wasn’t a template to our marketing,” and while it “did go to multiple doctors,” it only went
 23 to a handful of potential customers. *Id.* at 482:13-15. Moreover, Natera’s slides cut from the top
 24 of the email, the fact that Mr. Outzen sent the Harvard Study to the recipients with the email.
 25 Natera has agreed to consider adding this information.

26 Finally, Natera Slide No. 130 takes Mr. Nitin Sood’s testimony about a spreadsheet with
 27 2,964 calls, and claims that it shows that “Guardant shared Reveal’s key messages in nearly 3,000
 28 meetings with doctors.” This is simply not true, and nothing in either the spreadsheet or Mr. Sood’s

1 testimony supports this gross mischaracterization.

2 **Natera's Response: Nos. 11, 49, 127, 128, 130, 311.** The exhibits excerpted in these slides
3 were admitted into evidence, as was the testimony of the witnesses depicted on the slides. The
4 headings accurately describe Natera's theory of the case: that Natera's ads were in response to
5 false and misleading statements by Guardant (regardless of whether those false and misleading
6 statements appeared in formal advertisements).

7 With respect to the JPMorgan presentation, depicted in slide 49, Natera's position is laid
8 out in full in its opposition (Dkt. 824) to Guardant's trial brief. With respect to slide 130, both TX
9 710 and Mr. Sood's testimony are in evidence. Guardant's witness, Kristin Price testified testified
10 about the "Key Selling Messages" that it trained its employees to discuss with doctors around the
11 same time. TX-538.10. The evidence supports an inference that those "Key Selling Messages"
12 were used in Guardant salespeople's meetings with doctors, and Natera is entitled to make that
13 connection. To the extent Guardant disputes what the evidence shows, the jury should decide this
14 factual dispute.

15 Guardant raised no objection to Slides 128 and 131 during the parties' meet and confer.
16 Natera withdraws Slide 311.

17 **Guardant's Position: *ONLY*.** Natera Slide Nos. 44, 45, 117, 129, 312, and 313.

18 A large number of Natera's Slides also attack data that were reported in the Harvard Study,
19 and which cannot be the subject of Natera's claims. *See* Dkt. 326 at 36 ("As to Natera's 'artificially
20 inflated clinical performance metrics' counterclaim, the Court declines to evaluate scientific
21 conclusions from non-fraudulent data which are based on accurate descriptions of the data and
22 methodology.") While Natera has desperately tried to maneuver the Court's allowance of evidence
23 regarding "blinded" and "prospectiveness," most of Natera's attacks on the Harvard Study's results
24 have nothing to do with either of these issues.

25 Natera Slide Nos. 44, and 45 attack the Harvard's Study's reporting of its surveillance data
26 as a "reanalysis," inviting the jury to challenge the methodologies and conclusions of the study's
27 authors. Natera Slide No. 117 criticizes the Harvard Study's reported methodology for its
28 surveillance analysis, while Natera Slide No. 129 attacks Guardant for reporting 100% PPV at

1 landmark and 91% sensitivity in surveillance—both of which are drawn directly from the Harvard
 2 Study, and both of which are well characterized in the ad.

3 Natera Slide No. 312 provides *part* Guardant’s description of the landmark and
 4 surveillance setting data from the Harvard Study:

5 Finally, Natera takes out of context Dr. Parikh’s testimony to directly challenge her study’s
 6 reported finding that Reveal demonstrated 100% PPV and specificity at the Landmark setting. *See*
 7 Natera Slide No. 313.

8 **Natera’s Response: Nos. 33, 44, 45, 52, 68, 117, 118, 129, 312, and 313.** Natera’s
 9 arguments do not go outside the Court’s *Daubert* or Summary Judgment Orders. *See* Dkt. 326 at
 10 32:20-22 (“A claimant challenging the truthfulness of advertising that is ‘based on tests or studies’
 11 may satisfy its burden of demonstrating falsity ‘by showing that the tests did not establish the
 12 proposition for which they were cited.’”). Both Slides 33 and 52 show that the Parikh Study *does*
 13 *not support Guardant’s advertising claims*, an issue distinct from that raised by Guardant’s
 14 purported objection based on *ONY*.

15 Slides 44, 45, and 118 all show that the “surveillance” reanalysis was the result of
 16 Guardant’s *unblinding* and was *retrospective*, which was expressly allowed by the Court. Dkt.
 17 509 at 29 (“Natera asserts it should be able to argue that the 91% sensitivity metric was deemed
 18 unreliable if the study was indeed not prospective because the study calculated the sensitivity
 19 figure retrospectively, and this is akin to manipulating data. . . . The Court finds that this evidence
 20 is conditionally relevant. To the extent that Natera is able to establish a nexus between aspects of
 21 the study, e.g., the 1-year cut-off date and the purportedly fraudulent aspects of the study (i.e., that
 22 it was not blinded), this evidence may be relevant. It shows the unblinded-ness was
 23 consequential.”); *id.* at 26 (“[T]he Court’s summary judgment order and Betensky Daubert Order
 24 stands for the proposition that claims attacking the Parikh Study for falsely mischaracterizing its
 25 methods and findings, is an allowable basis for a Lanham Act claim.”). The evidence shows that
 26 the decision to define the “surveillance” analysis the way that it was and the decision to include
 27 that analysis at all was made after Guardant was unblinded, with full knowledge of how the
 28 “surveillance” reanalysis would affect the reported sensitivity.

Slides 68, 129, 312, and 313 are all expressly about *Guardant's advertising*, not the Parikh Study, and thus do not implicate the Court's orders relating to ONY. And Guardant did not raise objections to slides 312 and 313 during the parties' meet and confer, or at any time before sending its lengthy written objections at 4:32 p.m. today. For slide 129, TX-538 is already in evidence, and the slide heading uses the exact language from that exhibit. The witness's testimony is also accurate and in evidence. The purpose of the slide is to demonstrate that Guardant broadly advertised Reveal, and to indicate what Guardant was saying internally about what its "key selling messages" should be.

Guardant's Position: Puffery. Natera Slide Nos. 13, 47.

On summary judgment, this Court held that a reference to Reveal as offering "industry leading performance" is non-actionable puffery. Dkt. 326 at 40:

Guardant's "industry-leading performance" statement is mere non-actionable corporate puffery. *See City of Plantation Police Officers Pension Fund v. Meredith Corp.*, 16 F.4th 553, 557 (8th Cir. 2021) (holding that the term "'industry-leading position'" is a "paradigmatic example[] of the kind of 'vague' and 'optimistic' rhetoric that constitutes corporate puffery"). This district court has construed a company's statement that its product is "industry-leading" as puffery. *See, e.g., Taleshpour v. Apple Inc.*, No. 5:20-cv-3122, 2021 WL 1197494, at *9 (N.D. Cal. Mar. 30, 2021); *In re Pivotal Secur. Litig.*, No. 3:19-cv-3589, 2020 WL 4193384, at *14 (N.D. Cal. Jul. 21, 2020).

Natera repeatedly styles just such puffery as actionable advertising claims, including "best in class," Natera Slide No. 13:

Natera's Ads Responded to Guardant's Claim that Reveal Suddenly Was Best-in-Class



Helmy Eltoukhy
Co-CEO

“

I'm confident from recent data that our LUNAR-1 assay for recurrence monitoring is best-in-class from both a performance and clinical workflow perspective.

We really see no deficit or no reduction in sensitivity versus some of these other methods that they're sequencing the tumor, but they're kind of just simply looking at a few mutations in the blood and then tracking them.



TX-1308

”

See also Natera Slide No. 47 (virtually identical slide with different header).

Natera's Position: Slides 13 and 47 contain text excerpted from an admitted exhibit. For Slide 13, Natera intends to argue that Dr. Eltoukhy's statements prompted Natera's response, as previous public information presented from the Parikh Study showed a lower sensitivity (i.e., 69% longitudinal sensitivity). Dr. Eltoukhy publicly claiming “best-in-class” performance in November 2020, prior to the announcement of the launch of Reveal and the publication of the Parikh Study, counters Guardant's anticipated argument that Natera began, e.g., Project Solar before Guardant ever launched its product and before any data was made public.

Guardant's Position *Summarizing evidence not in the record.* Natera Slide Nos. 266, 267, and 269 each summarize documents that were never admitted in the record

Natera's Position: Dr. Stec testified to the exact categories, numbers, and significance of the material on these demonstratives. Day 8 Trial Tr. at 1862-1865.

Guardant's Position: *Misleading.* Finally, a number of Natera's slides are simply misleading, including Natera Slide Nos. 16, 71, 74, 75, 106, 119, 122, 124, 150, 155, 156, 157, 158, .

Natera's Position: There is nothing “misleading” about any of these slides, essentially all of which simply excerpt testimony or admitted exhibits and provide a descriptive title or a title that

1 explain the significance of the evidence to Natera's argument.
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Natera's Objections to Guardant's Closing Demonstrative Slides.

Pursuant to the Court's instructions, Natera provides the following objections to Guardant's closing demonstratives.

I. The Figures in Natera's Performance Comparison Are Not "FALSE" (Slide 1)

Natera's False Advertising			
Signatera vs. Reveal performance comparison			
	Signatera	Reveal	
Validation data published or presented (# patients analyzed)	> 2,000 ^{1,2}	< 150 ^{4,5}	
Pre-surgical sensitivity in CRC	89–94% ^{1,3}	47% ⁴	FALSE
Failure rate in CRC – tissue and plasma combined	< 3% ³	12–14% ⁴	FALSE
Number of blood tubes required	2	4	
Diagnostic lead time vs. radiographic recurrence in CRC (avg)	8.7 months ¹	~4 months ⁴	FALSE
Post-surgical NPV/PPV in CRC (30 days post-surgery)	88% / 100% ¹	not reported ⁴	FALSE
Serial longitudinal NPV in CRC	97% ¹	82% ⁴	FALSE
Serial longitudinal Hazard Ratio in CRC	43.5 ¹	11.4 ⁴	FALSE
Serial longitudinal sensitivity in CRC	88–94% ^{1,2}	69% ⁴	FALSE
Quantitation of ctDNA burden for monitoring purposes	Tumor copies per mL	none	

*Calculations derived from study data.
¹Reinert T, Hainsworth JV, Chinnaiya S, et al. Analysis of plasma cell-free DNA by ultrahigh sequencing in patients with stage I to II colorectal cancer. *JAMA Oncol.* 2019;5(5):1124–1131.
²Parikh A, et al. Natera's Plasma-Only Circulating Tumor DNA Assay in Colorectal Cancer Patients. *Clin Cancer Res* April 26, 2021.
³CRCCTA ATT site on file.
⁴Parikh A, et al. Natera's Plasma-Only Circulating Tumor DNA Assay in Colorectal Cancer Patients. *Clin Cancer Res* April 26, 2021.
⁵Vallet A, et al. Clinical impact of ultrahigh sequencing tumor DNA after total neoadjuvant treatment in locally advanced rectal cancer: A biomarker study from the GEMCAD 1402 Trial. *Clin Cancer Res* April 1, 2021.
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Slide 1 contradicts the Court's Summary Judgement Order ruling as a matter of law that "all Natera's advertising statements at issue are directly derived from the Reinert study and the Parikh study" and "[t]he numbers are not literally false on their face." Dkt. 326 at 13. Slide 1 is a version of Natera's Performance Comparison (TX-126) that improperly puts a large "X" next to the figures in the chart and labels them as "FALSE." There is no evidence that any of these figures in TX-126 are false, as the Court expressly ruled and the trial record confirmed. Trial Tr. at 1271:1-6 ("Q. And you're not disputing that the citations in each of the two columns, those are correct, are you? A [DR. HEITJAN]: I am not disputing the citations, no."); *see also id.* at 1271:7-1272:10, 1282:9-11, 1728:9-1729:3, and 1739:10-1739:20. Guardant should not be permitted to mislead the jury by suggesting these numbers are false.

Guardant's Response.

Natera mischaracterizes this Court's Summary Judgment Order. While the slide does not use the term "literally false," this Court held that each of Natera's comparisons could be found by the jury to be literally false by necessary implication. Dkt. 326 at 13-25 The slide fairly and accurately represents Guardant's fundamental claim in this case that the various performance comparisons Natera made in its commercial advertising were false.

II. Guardant's Demonstratives Have No Support In The Trial Record And Should Be Excluded At Least Under FRE 403 (Slides 11, 14, and 42)^{3 4}

Slide 11 is a flowchart entitled "What Doctors Would Need To Do To See Natera's Comparison Is False." It lists eight steps, but contains no citations to record evidence. During the meet and confer about Guardant's slides, it stated that pages 1251, 1253, and 1272 from Dr. Heitjan's testimony support this flowchart. But they do not. That testimony discusses confidence intervals for a single metric in the Reinert study, the impact of prevalence on NPV and PPV, and includes Dr. Heitjan's opinion that "[t]here's a lot of information missing" from Natera's performance comparison. It does not include any testimony about what doctors "would need to do" or would do, and does not address most of the "steps" in the flowchart in Guardant's slide.

³ In the original slides that Guardant served, slides 6 and 38 contain bar charts that appear to be demonstratives, but in fact are mere touched-up screenshots from TX-145, which is *not in evidence*. When the parties met and conferred, counsel stated that it would "modify slightly" slides 6 and 38 but would keep the figure substantively the same. Minutes before Natera had to file these objections, Guardant served substantively revised versions of slides 6 and 38. In view of the revisions, Natera no longer objects to slides 6 and 38. However, Natera was forced to spend time to meet and confer and brief this issue only for Guardant to retract at the last minute. More generally, it raises concerns that Guardant will seek to argue in its closing about issues that are not in evidence, as it intended to do in the initial version of the slides it provided. Guardant also has three slides (25, 27, and 29) that cite to TX-360, which was not admitted into evidence on the record, but that Natera is agreeing to allow in the interest of narrowing disputes. More generally though, especially given Guardant's repeated loaded questions during trial that simply spoke to "evidence" that was not admitted, Natera is concerned that Guardant will use its argument as an opportunity to discuss issues that are not in evidence.

⁴ Additionally, Natera has been asking Guardant repeatedly for the last two weeks how it proposes to submit TX-286 (the 7,000+-page compilation) to the jury. Guardant has brushed off Natera's requests every time. On this morning's conferral, Guardant assured Natera it would provide a proposal by 11:00 am this morning. As of this filing, Guardant has not provided any proposal, and so the issue remains unresolved.

1267:7-1268:20 (“Q: You’re not providing any opinions in this case, are you, about the views or beliefs of medical oncologists; right? A: I am not. . . . Q: So, Dr. Heitjan, you really don’t know anything about any purchasing or ordering decisions when it comes to Signatera and Reveal; right? Fair? A: Yea, I don’t know about that.”).

Slide 14 is a timeline that depicts Project Solar beginning in January 2021 and continuing through 2021, 2022, and August 2023. There is no citation for Project Solar continuing that long, and no evidence supporting it. In fact, the only evidence from trial is that Project Solar ended in 2021. 544:11-544:13 (Dr. Masukawa: “Q. This doesn’t include the amounts Natera spent on Project SOLAR in 2022? A. There was no Project SOLAR in 2022.”)

Slide 42 far exceeds the little evidence Guardant introduced regarding the Reinert Study⁵ and introduces attorney speculation masked as fact about the Reinert Study without any trial record support. **First**, the slide refers to “Natera” misleadingly as a monolith (e.g., “Natera unblinded to sample order,” “Natera conducts initial analysis unblinded to sample order,” “Natera reports initial analysis and is unblinded to clinical data,” “Natera “performs “unblinded reanalysis” and changes results”). In stark contrast to the record of Guardant’s analysts being unblinded, there is nothing in the record that supports an argument that the same Natera person(s) who were unblinded were analyzing the samples. Moreover, nothing in the record shows or even suggests that anyone at Natera “conduct[ed] initial sample analysis unblinded to sample order” or that anyone at Natera “perform[ed] ‘unblinded reanalysis’” and changed results. Dr. Andersen only testified generally that “Natera” was unblinded (Dkt. 821-1 at 31:16-31:23) and clarified, for example, that Dr. Shruti Sharma was involved in “the analysis” NOT the specific “ctDNA analysis.” *Id.* at 158:7. There is no record of *who* at Natera was conducting the “ctDNA analysis.” To the extent that Guardant seeks to argue that if one person at Natera was unblinded, then everyone involved was unblinded,

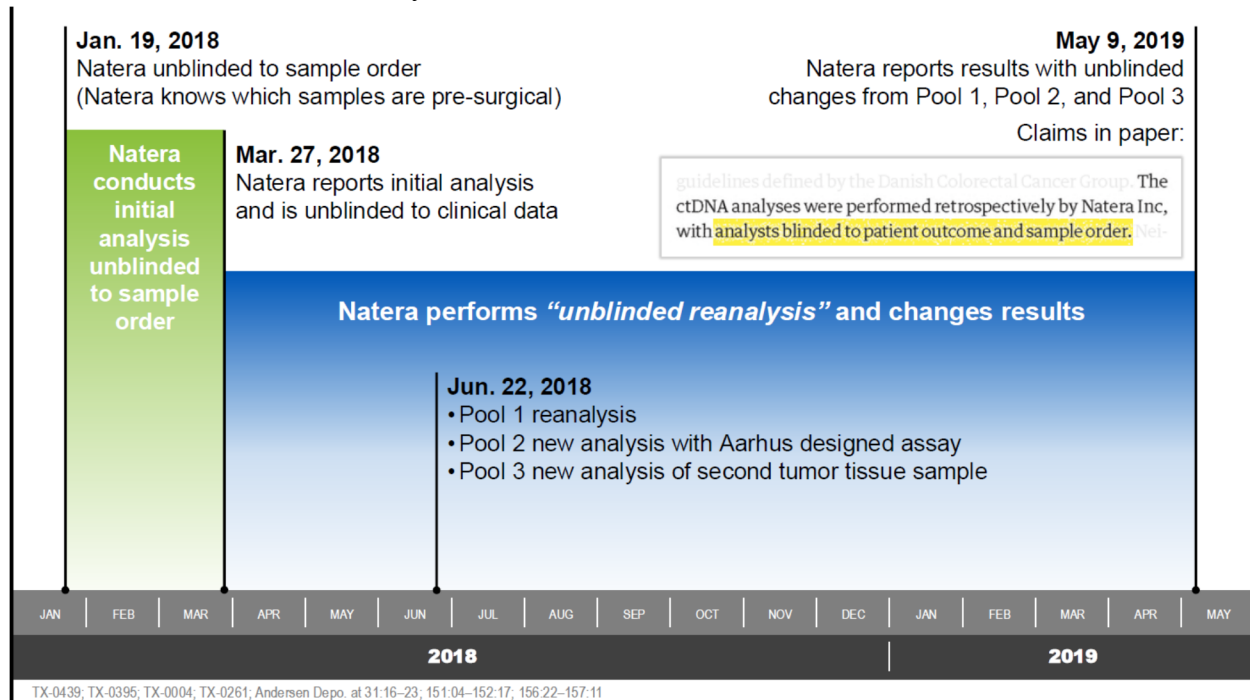
⁵ Nor does the Reinert Study have any bearing on the falsity of the Parikh Study’s representations as a “blinded” and “prospective” study. Trial Tr. 1850:15-18 (Dr. Betensky: “Q. Does the Reinert study in any way have any bearing on your opinions whether the Parikh study can be characterized as blinded or prospective? A. No, it does not. It’s -- they’re independent studies.”).

there is no support in the record to support such an inference. **Second**, the June 22, 2018 timepoint on Slide 42 is misleading. TX-261 only shows the date the results were reported, not the date of the analysis. **Third**, the May 9, 2019 timepoint exceeds the scope of the trial record including because Guardant has not adduced any evidence to suggest that “Natera” made any changes or that any changes from Pool 1, Pool 2, Pool 3 were published in the Reinert paper (TX-4).

Guardant’s Response. Slide No. 11 is proper argument, based on, and consistent with, testimony from both Guardant’s lay witnesses (Dr. Odegaard, Ms. Price, Ms. Raymond), as well as Dr. Heitjan. E.g., Trial Tr. 1251, 1253, 1272.

Slide No. 14 refers to the “Anti-Reveal Campaign Impact,” and Natera’s objection mischaracterizes both the slide and the evidence presented at trial. The Slide refers specifically to the ongoing “impact” of the Project SOLAR campaign. Testimony from Guardant’s lay witnesses and its expert Mr. Malackowksi (and even Natera’s own expert witness) demonstrates that this “impact” is continuing. Trial Tr. 1908:24-1909:7 (“one of the things” Dr. Stec’s regression analysis controlled for was “the impact of the false and misleading statements made by Natera”).

Slide No. 42 aptly summarizes the testimony of Dr. Andersen and the exhibits submitted in connection with his testimony:



For example, Dr. Andersen testified at Andersen Day 2 Dep. 150:25-151:07:

What does it say at the bottom? Is that all the way to the bottom?

Oh, my goodness. Oh, that is not how I remember it.

Q. So I am going to have to ask you again. Once you've looked at this. It does mean that Natera was unblinded for sample order?

A. It would appear so.

See also Andersen Day 2 Dep. 152:10-17

THE WITNESS: Oh, my goodness, we did it.

That's what we did.

Q. BY MS. JENSEN: And we know that the samples that were taken presurgery?

A. Those are the preoperative samples.

Q. And back then we knew that the patients have cancer; is that correct?

A. Correct.

There is absolutely no dispute that Natera in fact re-analyzed samples after it was unblinded, and that the reanalysis of the unblinded samples led to different results than what had been achieved using blinded samples. Andersen Day 2 Dep. 146:08-19:

[Q.] You confirmed on Wednesday, and earlier, your explanation, Natera reanalyzed some of the samples after they were unblinded; correct?

A. Yes.

Q. And you confirm that, after my review, you also remembered and agreed that the reanalysis of some of the patients' samples changed some of the tests changed some of the CtDNA results?

A. Correct.

In sum, Slide No. 42 briefly and accurately summarizes the evidence in the record regarding Natera's use of unblinded data. .

1 Dated: November 21, 2024

A&O SHEARMAN

2
3 By: /s/ Saul Perloff
Saul Perloff

4 Attorney for Plaintiff/Counter-Defendant
5 GUARDANT HEALTH, INC.

6
7 DATED: November 21, 2024

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FILER'S ATTESTATION

Pursuant to Civil LR 5.1(i)(3), the undersigned hereby attests that concurrence in the filing of this **JOINT SUBMISSION RE CROSS-OBJECTIONS TO OPENINGS** has been obtained from counsel for Natera, Inc. and is electronically signed with the express permission of Natera's counsel.

Date: November 21, 2024

By: /s/Saul Perloff
Saul Perloff

Attorney for Plaintiff/Counter-Defendant
GUARDANT HEALTH, INC.

CERTIFICATE OF SERVICE

In accordance with Local Rule 5-5, I certify, that on November 21, 2024, this document, filed with the Court through the CM/ECF system, will be sent electronically to the registered participants at their e-mail addresses as identified in the Notice of Electronic Filing (NEF). Non-CM/ECF participants will be served via First-Class Mail.

I certify under penalty of perjury that the foregoing is true and correct. Executed this 21st day of November.

/s/ Saul Perloff
Saul Perloff